From: Joseph Mazzarese
Sent: Wednesday, April 09, 2008 4:02 PM
To: Markush.Comments
Subject: Comments on Proposed Rule Changes

Dear Sir:

The attached letter contains comments regarding the proposed changes to rules relating to alternative claim language. Please take these comments into consideration.

Thank you.

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April 9, 2008

The Honorable Jon Dudas
Under Secretary of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office
Mail Stop Comments
P.O. Box 1450
Alexandria, VA 22313-1450

Re: **Notice of Rulemaking entitled, "Examination of Patent Applications That Include Claims Containing Alternative Language"**

Dear Under Secretary Dudas:

Wyeth appreciates the opportunity to provide comments on the U.S. Patent and Trademark Office ("PTO") proposed rules directed to "Examination of Patent Applications That Include Claims Containing Alternative Language," published at 72 Fed. Reg. 44992 (August 10, 2007). This letter addresses proposed changes to 37 C.F.R. 1.140(a), 1.142(d), 1.146(b), and 1.75 (a) and (j).

Wyeth is one of the world's largest research based pharmaceutical and health care products companies. It is a leader in the discovery, development, manufacturing and marketing of pharmaceuticals, biotechnology products, vaccines and non-prescription medicines that improve the quality of life for people worldwide. Wyeth spends billions of dollars on research and development each year to invent and bring to market new health care products that benefit the public.

The United States is the world leader in the pharmaceutical industry and derives a great deal of economic and health benefits from the success of the industry. This industry is research-driven and requires very large investments of both money and labor. It typically requires an investment of approximately 7-15 years of effort for a new pharmaceutical product to be discovered, developed, and approved by the FDA before it can be marketed. It also takes an average R&D investment of

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approximately $1 billion or more for each new pharmaceutical product that reaches the market.

In order to keep funding this important work, Wyeth and other research-driven pharmaceutical companies must be able to protect their investments by obtaining strong patent protection for their inventions. The pharmaceutical field is highly competitive, and includes many domestic and foreign companies having a great deal of expertise in the field. Because competitors are highly capable of copying inventions or finding competitive variations thereof, adequate patent protection is crucial to our business.

New classes of pharmaceutical compounds are typically quite complex and often cannot reasonably be described without using the type of alternative language that the proposed rules seek to curtail. The scope of a claimed genus is based on both extensive research (often including making hundreds of compounds within the genus) and the inventors' expertise and knowledge of the field, and must be adequate to provide protection against competitors. Without such patent protection research on new and important health care products could not be funded.

Wyeth is concerned that the proposed new rules set forth in the Notice will adversely impact Wyeth's ability to adequately protect its inventions and investments, and our country's leading position in the industry.

II. Detailed Comments

A. 37 C.F.R. 1.75(a), 1.140(a) and 1.142(d)

Under the proposed changes in 37 C.F.R. 1.75(a), 1.140(a) and 1.142(d): (1) each claim would be limited to a single invention; (2) two or more independent and distinct inventions could not be included in a single claim; (3) a claim that reads on multiple species using alternative language would be a single invention only if they share a feature "essential for a common utility" or are prima facie obvious over each another; and, (4) a claim reciting both an elected and non-elected invention would be objected to, and the non-elected invention would have to be canceled.

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Many aspects of these changes are contrary to the patent laws and beyond the scope of the USPTO's rule-making authority. They are also certain to be harmful to the pharmaceutical industry.

The USPTO has no authority to promulgate the proposed rule that each claim would be limited to a single invention. Indeed, it is established law that a single claim may not be rejected under 35 U.S.C. 121 on the basis that it contains independent and distinct inventions. Such a rejection "violates the basic right of the applicant to claim his invention as he chooses." *In re Weber*, 198 USPQ2d 328, 331-332 (CCPA 1978).

> [A]n applicant has a right to have *each* claim examined on its merits…. If, however, a single claim is required to be divided up and presented in several applications, that claim would never be considered on its merits. The totality of the resulting fragmentary claims would not necessarily be the equivalent of the original claim. *In re Weber* at 331.

Under the proposed rules, claims reading on multiple species using alternative language would be a "single invention" only if they share a feature "essential for a common utility" or are prima facie obvious over each another. This is completely vague, and, to the extent one can determine its meaning, contrary to the law.

The court in *In re Harnish*, 206 USPQ2d 300 (CCPA 1980) addressed the issue of rejection of a claim as containing an "improper Markush group". The *Harnish* court found that a Markush group was proper where the claimed compounds all had the same utility, but suggested that a claim perhaps could be rejected as improper under a unity of invention analysis "where *unrelated* invention are involved - inventions which are truly independent *and* distinct." *In re Harnish* at 305-306 (*emphasis* in the original).

In the *Harnisch* decision, the court determined that the claim recited a proper Markush group because the claimed compounds **shared a common utility** (in that case as dyes) and **possessed a "single structural similarity"** (as coumarins). The requirement in the Notice of proposed rulemaking that the "feature" essential for a common utility be a **common structure, material or act**

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necessary for at least one shared specific substantial and credible utility goes far beyond the *Harnisch* decision, as it requires 1) a link between these two criteria that is absent in *Harnisch;* and 2) knowledge of what "features" are "essential" for utility at the time of filing an application. There has never been any such requirement in the patent laws, for at least the reasons that in many arts, such as the chemical and pharmaceutical arts, there simply may not be a single "feature" that is "essential." Moreover, even if such a feature or features were to exist, one may never know which features of a given compound or series of compound are "essential" for function.

In the years since the *Weber* and *Harnish* decisions, Congress has not seen fit to change the law set forth in these decisions. "Congress has debated and considered whether it should grant the USPTO substantive rulemaking authority but has declined to do so." *Tafas v. Dudas*, No. 1:07-cv-00846-JCC-TRJ, slip opinion at 13 (E. D. Va. April 1, 2008). Therefore, the rules promulgated by the USPTO should follow the law stated in the *Weber* and *Harnish* decisions.

The proposed changes in 37 C.F.R. 1.75(a), 1.140(a) and 1.142(d) are contrary to the statute and case law. A single claim should never be subject to restriction or rejection under 35 U.S.C. 121, and should only be rejected as containing an improper Markush group where there is no unity of invention, i.e., where the claim covers unrelated inventions which are truly independent and distinct.

In addition to being contrary to law, the proposed changes are troublesome because they would adversely impact the ability of pharmaceutical companies and other inventors to adequately protect their important inventions. If the allowable content of a claim were restricted as has been proposed, the patentee's competitors would find it easier to identify a similar product not covered by the claims, but having the same function. Consequently, the patentee would not be able to benefit from the exclusive right that the patent should provide, and would not be able to recoup its R&D investments. It is not sufficient to provide that the invention may be patented in multiple parts through numerous divisional applications, since it would be difficult or impossible to obtain the same scope of coverage in many cases. Furthermore, multiple applications cost much more money than a single application; given the increasingly higher fees charged by the

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USPTO, the cost of patent protection would become much more burdensome to patentees.

The proposed changes to 37 C.F.R. 1.75(a), 1.140(a) and 1.142(d) should not be implemented. Any changes to these regulations should be consistent with the patent statute and the case law.

B. 37 C.F.R. 1.75(j)

Proposed 37 C.F.R. 1.75(j) would impose the following conditions on claims using alternative language: (1) the number and presentation of alternatives does not make the claim difficult to construe; (2) no alternative is defined as a set of further alternatives within the claim; (3) no alternative is encompassed by any other alternative within a list of alternatives, unless there is no other practical way to define the invention; and (4) each alternative within a list must be substitutable one for another.

The term "difficult to construe" is completely vague, and is not the proper legal standard for a patent claim. The correct standard is found in 35 U.S.C. 112: a claim must particularly point out and distinctly claim the subject matter which applicant regards as his invention. It is irrelevant whether it is "easy" or "difficult" to construe.

In the pharmaceutical arts, as in many other arts, inventions are increasingly complex. To require that the invention must be simple to understand would be to prevent patent claims to complex subject matter. The USPTO has no authority to limit patentable subject matter to inventions that are easy to construe.

Furthermore, applicants would have no way to know which claims will be considered "difficult to construe" when drafting claims, and it is very likely that each examiner would apply the rule differently. Adoption of this rule will lead to countless petitions and lawsuits arguing over the level of difficulty of the claim language.

Further, although the Office wants claims to be simpler and easier to understand, the proposed prohibition on "nested" Markush groups would likely result in longer claims that are harder to understand. Consider, for example, this relatively simple claim: "A compound of the formula

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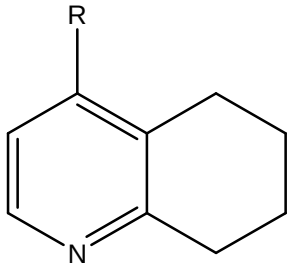

wherein R is selected from the group consisting of $CR^1R^2R^3$ and NR^1R^2, and R^1, R^2, and R^3 are independently selected from the group consisting of H, halogen and C_1-C_6 alkyl."

Under the proposed rules, this claim would be prohibited because R is a "nested" Markush group. However, without such nested Markush groups, R would have to be defined as a string of at least several hundred different groups[1]. This would make it harder for the examiner (and the public) to determine what is included in the long list, make it easier for the drafter to make errors in the claim, and also make the claim unnecessarily long.

Significantly, most new pharmaceutical genera are much more complex than the example above. Using nested Markush groups, patentees are able to describe in definite terms the scope of the subject matter they claim as their invention. Without nested Markush groups, these claims would become prohibitively lengthy and would likely be deemed "difficult to construe." In such a case, Applicants would be forced to file many (perhaps tens or hundreds) of applications to adequately protect their inventions. This would be a practical impossibility for virtually all patentees, and would result in a denial of Applicants' rights under the law. Clearly, the PTO has no authority to promulgate rules having such a substantive effect. *Tafas v. Dudas*, No. 1:07-cv-00846-JCC-TRJ, slip opinion (E. D. Va. April 1, 2008).

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[1] R^1, R^2, and R^3 are each one of eleven possible groups, not counting any isomers, which equates to well over 300 possible $CR^1R^2R^3$ and NR^1R^2 groups. Listing each isomer separately, the number of groups is in the thousands. If the alkyl groups were permitted to be substituted with 1-3 halogen atoms, the number of individual substituent groups would be many times larger.

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Additionally, regulations that would constrict patentees' freedom to describe their invention should not be made unless it is shown that some important benefit will result, and that patentees' substantive patent rights will not be compromised. Proposed 37 C.F.R. 1.75(j) has no apparent benefit, and, as discussed above, could well compromise patentees' substantive rights to claim the full scope of their inventions.

C. 37 C.F.R. 1.146(b)

It is proposed that after an election of species is made in a generic claim, if any species in the genus is found unpatentable then the claim may be restricted to the elected species. This proposal essentially would permit a generic claim to be restricted to a single species, even if it contains a great deal of additionally allowable subject matter, merely because one species within the claimed genus is found to be unpatentable.

Under this proposal, in the example claim above, if the species where R = CH_2Cl were the elected species, and the species where R = NH_2 were found not patentable, the claim would be limited to R = CH_2Cl and the rest of the subject matter would need to be canceled. There is no logical reason why, for example, the compound where R = $C(CH_3)_3$ should be canceled merely because the NH_2 compound is not patentable. Once the search has been expanded beyond the elected species, it is most efficient for the entire claim to be examined together, not broken into numerous divisional applications which would each be separately searched and examined.

The result of this proposal would be that many patentees would not be able to have their generic claims examined and considered in the form that they consider best to describe their respective inventions. It would encourage examiners to force patentees to convert generic claims into narrow species claims whenever an unpatentable species within the claim could be found.

Where an unpatentable species of a genus is identified, the proper action is a rejection of the claim. Patentee should then be permitted to amend the claim to remove the basis for the rejection. A single claim should not be restricted under 35 U.S.C. 121, regardless of whether it contains an unpatentable species. See, *In re Weber*, at 331-332.

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The USPTO has failed provide any reason why this proposed change is necessary or beneficial. Furthermore, the USPTO has no legal authority to limit a generic claim to a single species merely because another species within the claim is unpatentable.

D. The Proposed Changes Will Not Achieve Their Goals

The Notice indicates that the purpose of the proposed changes is to ease the burden on USPTO resources resulting form searching and examining claims using alternative language. However, it has not been shown that these changes will achieve that goal. It is foreseeable that implementations of the proposed regulations would lead to many more patent applications to closely related inventions that could have been searched and examined more efficiently in one application. Although these changes in some cases may reduce the examiner's work from the perspective of a single application, the overall work load of the examining corps will not be reduced, but may be increased.

The Notice has also indicated a goal of enhancing the quality of patents. It is not clear what criteria the USPTO uses to judge quality. However, to the pharmaceutical industry it is important to be able to obtain patents that have sufficient scope to protect the inventions and large investments of the patentee company; we see the proposed restrictions on claim scope as mechanisms for reducing the quality of our patents.

E. The USPTO Has Failed To Provide Credible Evidence That The Proposed Changes Will Be Beneficial To The Public

The Notice does not show that the USPTO has studied the impact that the proposed changes would have. No evidence is presented to show that the changes would improve patent quality or reduce the overall work load of the examining corps. No analysis is provided of the substantive impact the changes would have on patent rights, the consequences to our future health care, or the burden on patentees and the public due to an increase in the number of patent applications. No analysis or estimate of the increase in the number of applications is provided, which suggest that further analysis is needed.

The USPTO has provided some rudimentary statistics regarding the potential impact of the proposed regulations on small entities. However, the greatest impact will not be on small entities, particularly in the pharmaceutical

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industry. The overall impact of the changes cannot be appreciated without further analysis.

III. Suggestions

It is appreciated that it is difficult for the examining corps to keep up with the ever-increasing number and complexities of patent applications. Examiners often find that they have not been allotted enough time to properly search and examine complex applications, and would like to have less work per application.

In view of these challenges, the USPTO has been trying to reduce the amount of work an examiner must do on each case by drafting new regulations that would force applicants to put less subject matter into each application. However, this approach is misguided. It would force applicants to file more applications, leading to a larger backlog of cases in the Office. In many cases, it would prevent applicants from claiming the full scope of their inventions, which will adversely and disproportionately impact the pharmaceutical industry.

The ever-increasing number and complexity of inventions cannot be stopped by regulatory fiat. It is a necessary consequence of advancing technology. To deal with this, the USPTO should focus on is increasing efficiency and flexibility in searching and examining applications.

The most efficient way to handle an application is to have it searched and examined all together, rather than to break it up into multiple cases which would require multiple searches and examinations. The USPTO should give examiners more time to do their work when a complex application is being examined, and discourage restriction practice, to keep the number of applications down and allow examiners to work more efficiently. This would require a new management system in which management would judge how much time is needed for an each application and provide the examiner with the appropriate time (and credit) for each case. By keeping applications together, there would be less applications and increased efficiency.

With the computer search capabilities available to examiners today, it is not as burdensome to search related inventions as it was in the past. For example, an entire genus of compounds can be readily searched by structure. It is highly inefficient to have this same search done multiple times.

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IV. Conclusion

While Wyeth appreciates the USPTO's desire to ease the burden of the examining corps, Wyeth strongly believes that the USPTO lacks the statutory authority to do so by making regulations that compromise the statutory rights of patentees, as the proposed changes do. Wyeth also believes that these changes would have a strong negative impact on the pharmaceutical industry and on the industry's ability to continue to improve health care throughout the world.

Instead of proposing rules that would curtail Applicants' ability to protect their inventions, the USPTO should look for ways to improve the efficiency and flexibility of its processes. Changes in the regulations should only be made where there is good evidence that these changes will be more beneficial than harmful, and where they comply with the patent law. The proposed changes in the regulations fail to meet these standards and should not be implemented.

Wyeth thanks the PTO for the opportunity to provide comments.

Very truly yours,

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